



Patient Information Sheet

Mifepristone (marketed as Mifeprex)

This is a summary of the most important information about Mifeprex. For details, talk to your healthcare professional.

FDA ALERT– [07/2005] FDA is aware of four women in the United States who died from sepsis (severe illness caused by infection of the bloodstream) after medical abortion with Mifeprex and misoprostol. Sepsis is a known risk related to any type of abortion. The symptoms in these cases were not the usual symptoms of sepsis. We do not know whether using Mifeprex or misoprostol caused these deaths. Patients should contact a healthcare professional right away if they have taken these medicines and develop stomach pain or discomfort, or have weakness, nausea, vomiting, or diarrhea with or without fever, more than 24 hours after taking misoprostol. These symptoms, even without a fever, may indicate sepsis. Make sure your healthcare practitioner knows you are undergoing a medical abortion.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

What Is Mifeprex?

Mifeprex is used to end an early pregnancy. It blocks a hormone needed for your pregnancy to continue. It is not approved for ending later pregnancies. Early pregnancy means it has been 49 days (7 weeks) or less since your last menstrual period began. When you use Mifeprex (Day 1), you also need to take another medicine, misoprostol, 2 days after you take Mifeprex (Day 3), to end your pregnancy. About 5-8 out of 100 women taking Mifeprex will need a surgical procedure to end the pregnancy or to stop too much bleeding.

Who Should Not Take Mifeprex?

Do not take Mifeprex if:

- It has been more than 49 days (7 weeks) since your last menstrual period began.
- You have an IUD. It must be taken out before you take Mifeprex.
- Your doctor has told you that you have a pregnancy outside the uterus (ectopic pregnancy).
- You have problems with your adrenal glands (chronic adrenal failure).
- You take a medicine to thin your blood.
- You have a bleeding problem.
- You take certain steroid medicines.
- You cannot return for the next 2 doctor's office visits.
- You cannot easily get emergency medical help in the 2 weeks after you take Mifeprex, if you need it.
- You are allergic to mifepristone, misoprostol, or medicines that contain misoprostol, such as Cytotec or Arthrotec.

What Are The Risks?

The following are the major possible risks and side effects of Mifeprex therapy. This list is not complete.

- **Cramping and Bleeding** are expected with this treatment. Usually, these symptoms mean that the treatment is working. But sometimes, you can get cramping and bleeding and still be pregnant. This is why you must return to your healthcare professional on Day 3 and on about Day 14. See the *Medication Guide* for more information on when to return to your healthcare professional. If you are not already bleeding after taking Mifeprex, you probably will begin to bleed once you take misoprostol, the medicine you take on Day 3. Bleeding or spotting can be expected for an average of 9–16 days and may last for up to 30 days. Your bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue. This is an expected part of ending the pregnancy.

Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth. Prompt medical attention is needed in these cases.

Be sure to contact your healthcare professional right away if you have any of the following:

- **Heavy Bleeding.** Contact your healthcare professional right away if you bleed enough to soak through two thick full-size sanitary pads per hour for two consecutive hours or if you are concerned about heavy bleeding. In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical abortion/D&C) to stop it.
- **Abdominal Pain or Feeling Sick.** If you have abdominal pain or discomfort, or you are feeling sick with symptoms including weakness, nausea, vomiting or diarrhea, with or without fever, more than 24 hours after taking the misoprostol, you should contact your healthcare professional right away. These symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).
- **Fever.** In the days after treatment, if you have severe abdominal pain or a fever of 100.4°F or higher that lasts for more than 4 hours, you should contact your healthcare professional right away. Fever may be a symptom of a serious infection or another problem.





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(including an ectopic pregnancy, a pregnancy outside the womb).

What Should I Tell My Healthcare Professional?

Before you take Mifeprex, tell your healthcare professional about all of your medical conditions and problems, especially if you:

- **Are Breastfeeding:** If you are breastfeeding at the time you take Mifeprex and misoprostol, discuss with your healthcare professional if you should stop breastfeeding for a few days.
- **Smoke** at least 10 cigarettes a day.

Can Other Medicines or Foods Affect Mifeprex?

Mifeprex and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

What Else Should I Know About Mifeprex?

- You must have 3 visits to your doctor's office during the treatment procedure. It is ***extremely important*** that you attend all three visits. Please read the *Medication Guide* for information on how to take Mifeprex.
- You can become pregnant again right after your pregnancy ends. If you do not want to become pregnant again, start using birth control as soon as your pregnancy ends or before you start having sexual intercourse again.

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